K061016

JUN - 8 2006

510(k) Summary

EBI® ESL® PEEK-OPTIMA® Spine System

Proprietary Name:	ESL® PEEK-OPTIMA® Spine System
Common Name:	Vertebral Body Replacement Device
Classification Name:	Spinal Intervertebral Fixation Orthosis, 21 CFR §888.3030
Product Code:	MQP
Predicate Device(s):	EBI® ESL® Spine Spacer System Interpore Cross International PEEK CAS
Contact Information:	Jennifer Harakal, Regulatory Affairs Specialist EBI, L.P. 100 Interpace Parkway Parsippany, NJ 07054 Phone: 973-299-9300 x2156
Date Summary Prepared:	May 15, 2006

Indications for Use

The ESL® PEEK-OPTIMA® is indicated for use in the thoracolumbar spine (i.e., T1 to L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The ESL® PEEK Spine Spacer System is also indicated for partial vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The ESL® PEEK-OPTIMA® is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

Device Description

This Special 510(k) submission is intended to reflect the addition of PEEK spacers to the existing ESL Spine Spacer System.

Substantial Equivalence

The subject ESL PEEK-OPTIMA Spine System is similar to its predicate devices with respect to intended use and basic design. Mechanical testing demonstrated comparable mechanical properties to the predicate components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2006

EBI, LP
% Ms. Jennifer P. Harakal
Regulatory Affairs Specialist
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K061016
Trade/Device Name: EBI® ESL® PEEK-OPTIMA® Spine System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: May 17, 2006
Received: May 18, 2006

Dear Ms. Harakal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061016

Device Name: EBI® ESL® PEEK-OPTIMA® Spine System

Indications For Use:

The ESL® PEEK-OPTIMA® is indicated for use in the thoracolumbar spine (i.e., T1 to L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The ESL® PEEK-OPTIMA® is also indicated for partial vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The ESL® PEEK-OPTIMA® is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

Prescription Use__X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061016